21. The method according to claim 16, wherein the monoclonal antibody is a chimeric or humanized antibody directed against IL-6 receptor.

22. The method according to claim 21, wherein the monoclonal antibody is humanized PM-1 antibody.

23. A method for suppressing sensitized T cell, comprising administering to a patient in need thereof a pharmaceutical composition comprising an antibody directed against interleukin-6 (IL-6) receptor and a pharmaceutically acceptable carrier.--

REMARKS

A prompt examination on the merits is respectfully requested.

Claims 14-23 are pending. Claims 1-13 have been rewritten as method claims wherein the T cell-mediated diseases are specified and the active ingredient, IL-6 antagonist, is specified as an antibody directed against IL-6.

Applicants note with appreciation the approval by the Examiner of the submitted drawings, the acknowledgment of the claim for priority and receipt of the priority documents, and the initialed PTO-1449 form.

The Examiner has requested the amendment of the specification include reference to a related application on the first page of the specification. This has been done.

Rejections under 35 USC 112, First Paragraph

Claims 1-13 have been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses.

As the rejection may pertain to the newly submitted claims, the following comments are offered. The biological material referred to by the Examiner is publicly available. The material can be obtained from depositories recognized under the Budapest Treaty, and patents referring to

the material have issued. The deposits and depositories are referred to in the specification. See, for example, the paragraph bridging pages 35 and 36 of the specification. Copies of the Budapest Treaty Rule 7.1 receipts are enclosed.

After considering these facts, if the Examiner still deems a declaration regarding removal of restrictions to access and to replacement of the biological material necessary, such a declaration can be provided.

Withdrawal of the rejection is respectfully requested.

Claims 1-13 have been rejected under 35 USC 112, first paragraph, as maintained by the Examiner, because the specification, while being enabling for the specific monoclonal anti-human IL-6 receptor antibody (PM-1) recited in claim 9, and the specific monoclonal anti-mouse IL-6 receptor antibody (MR16-1) recited in claim 7, and a method of treating delayed foot pad edema comprising administering said antibodies, said specification does not reasonably provide enablement for a "preventive" agent, or for "all possible" agents comprising IL-6 antagonists as active ingredients, or any agent that prevents or treats multiple sclerosis. The Examiner posits that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant respectfully traverses.

It is respectfully submitted that this rejection is not applicable to the new method claims. It should be noted that a variety of preparative techniques for the claimed antibody IL-6 have been described. Monoclonal techniques are taught starting, for example, on page 10. Recombinant techniques are taught starting on the last line of page 13. Altered antibody preparative techniques are taught starting on page 15. Working examples have been included.

The quality and quantity of the information provided, taken with conventional wisdom at the time the application was filed, has not been commented upon in terms of its sufficiency to permit practice of the invention as claimed without the exercise of undue experimentation.

Rejections under 35 USC 112, Second Paragraph

Claims 1-11 stand rejected under 35 USC 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicant respectfully traverses.

The rejected claims have been canceled. The language of the new method claims reflects the points raised in the Official Action.

The rejection is deemed avoided by the new claims.

Rejections under 35 USC 101 -- Double Patenting

Statutory Double Patenting

Claims 2-4, 6, 8-9 and 13 are rejected under 35 USC 101 as claiming the same invention as that of claims 1, 3 and 6 of U.S. Patent No. 5,670,373.

The new claims maintain a clear line of demarcation. Accordingly, the rejection is not applicable here.

Nonstatutory Double Patenting Rejection (obviousness-type)

Claims 1 and 10-12 stand rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,670,373. Applicants respectfully traverse.

The new claims are method claims which require the administration to a subject of an effective amount of antibody to accomplish a stated function. Considering the claim cited by the Examiner alone, and the fact that no secondary teaching is relied upon, there is no recognition of the activity required to determine the effective amount and its use in the claimed method. In light of this, it is submitted that the new claims represent a patentably distinct invention from the claims of the cited patent. The rejection, as stated, is not applicable to the new claims.

Anticipatory rejections

Claims 1-4, 6, 8-13 are rejected under 35 USC 102(e) as being anticipated by Tadamitsu Kishimoto (U.S. Patent No. 5,670,373).

It is agreed that Kishimoto teaches a humanized monoclonal antibody specific for IL-6 receptor (see Abstract and column 2, lines 11-39), which was shown to specifically bind to IL-6 receptor (column 4, line 45-column 5, line 41) and was disclosed to inhibit the binding of IL-6 to IL-6 receptor.

The new method claims avoid these teachings and should avoid an anticipatory rejection based thereon.

Claims 1-4, 5, 7-13 are rejected under 35 USC 102(b) as being anticipated by Kishimoto *et al.* (WO 96/11020).

It is agreed that Kishimoto *et al.* teaches a mouse monoclonal antibody specific for IL-6 receptor, named MR16-1, which was shown to specifically bind to IL-6 receptor and inhibit IL-6 induced uptake of H-thymidine by M146O.B SF2 cells (see page 20, line 5-page 21 line 14)

The new claims avoid these teachings and thereby avoid an anticipatory rejection based thereon.

Conclusion

Having addressed all the objections and rejections, the application is believed to be in condition for allowance and a notice to that effect is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 350292000800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: October 10, 2000 By: _____

Thomas G. Wiseman
Registration No. 35,046

Morrison & Foerster LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-1888
Telephone: (202) 887-1678
Facsimile: (202) 887-0763